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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,715	03/13/2002	Kenneth C. Waterman	PC11726AAKM	1953

7590 07/12/2005

EXAMINER
WEBMAN, EDWARD J

ART UNIT	PAPER NUMBER
1616	

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DATE MAILED: 07/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/099,715	WATERMAN, KENNETH C.	
	Examiner	Art Unit	
	Edward J. Webman	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *13 April 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-95* is/are pending in the application.

4a) Of the above claim(s) *43-56 and 71-93* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-42,57-70,94 and 95* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *7/11/02, 8/19/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicant's election with traverse of Group I, claims 1-70, 94, 95, an immediate release (compressible) coating, different drugs, and drugs in the core and second compressible layer in the reply filed on 10/20/04 and 4/13/05 is acknowledged. The traversal is on the ground(s) that no undue burden has been shown. This is not found persuasive because said burden has been shown by the classification of the composition and method in entirely different classes.

The requirement is still deemed proper and is therefore made FINAL.

The election of species requirements over same or different drugs and immediate or controlled release coatings are withdrawn.

Claims 1-42, 57-70, 94, 95 are active. Claims 43-56, 71-93 have been withdrawn from consideration.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 6-11, 13-15, 17-22, 70, 94, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Faour et al (US 6,004,582).

Faour et al teach a multilayered osmotic device comprising a first active agent in an outer lamina and a second agent in the core (abstract). An erodible polymer coat comprising poly (vinyl pyrrolidone) vinyl acetate copolymer between the internal semi-permeable membrane surrounding the core and the lamina containing the second active agent is disclosed (abstract). Tablets are specified (column 6 line 7). The examiner

takes notice under MPEP 2144.03 that tablets are recognized by one of ordinary skill to have a top, a bottom, and edges. The lamina containing the second active agent can be for immediate or controlled release (column 6 lines 11-15). The polymer coat can be slow, fast dissolving, or enteric (column 6 lines 58-59, column 7 lines 16-48). The second active agent can be the same or different from the first (column 6 lines 11-12). Plasticizers such as polyethylene glycol are specified for the semi-permeable membrane, lamina, and polymer coat (column 9 lines 1-20, column 12 lines 15-30). As to the claimed compression of layers, such is deemed a process limitation, not considered patentable during the prosecution of product claims before the USPTO. As to the claimed release rate and profile, they are met by the nature of the coating and lamina as described above. As to the claimed location of the second drug on the bottom side of the tablet, the polymer layer of Faour et al surrounds the core (see Figure 2), therefore including the bottom side of the disclosed tablet.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made

Claims 1, 6-22, 70, 94, 95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faour et al (US 6,004,582) in view of Johnson et al (US 6,171,618).

Faour et al is described above. Pseudoephedrine is specified (column 14 line 36). The reference does not teach the claimed ratios of layers, the claimed cetirizine,

the claimed polymer molecular weight, nor the claimed loci of the active agents in the device.

Johnson et al teach a dosage form combining controlled release of pseudoephedrine from the core of a dosage form and immediate release of cetirizine to ensure patient compliance. (column 1 lines 42-64).

It would have been obvious to one of ordinary skill to deliver pseudoephedrine from the core and cetirizine from the lamina of the Faour et al device to achieve the beneficial effect of ensuring patient compliance in view of Johnson et al. As to the claimed ratios of layers, the examples in Faours et al demonstrate suitable amounts; optimal ratios may be achieved by routine experimentation absent a showing of criticality. As to the claimed molecular weight of polyvinylacetate, Faour et al teach Kollidon VA64, a commercially available poly(vinylpyrrolidone)-vinyl acetate copolymer. One of ordinary skill would select the optimum molecular weight by routine experimentation absent a showing that the claimed range is critical.

Claims 1, 2, 6-11, 13-15, 17-25, 31, 35-41, 57-64, 66-67,70, 94, 95 are rejected under 35 U.S.C. 102(b) as being anticipated by Guittard et al (US 4,576,604).

Guittard et al teach an osmotic device with instant drug availability (title). A tablet with a top, bottom, and edges is specified (column 4 lines 59-60 and Figure 1). Figure 3 discloses a compartment containing a drug surrounded by a semi-permeable wall and a lamina external to the wall comprising an aqueous soluble or disintegrating material and another drug (column 5 lines 26-51). A drug can also be contained in the

semipermeable wall (column 5 lines 51-56). Figure 5 discloses a device like that of Figure 3 with a microporous lamina containing a drug and lying between the wall and the previous described lamina (column 5 lines 44-54). The microporous lamina delivers its drug by a controlled continous rate, whereas the erodible or soluble outer lamina can deliver its drug by immediately or over a period of time (column 6 lines 40-43 and lines 54-60). The drugs can be the same or different (column 7 lines 8-10). Polyethylene glycol is disclosed in the semi-permeable wall, the microporous lamina and the outer lamina (example 4 column 20 lines 7-15, examples 6-7 column 20 lines 55-62 and column 21 lines 4-13). As to the claimed compression of layers, such is deemed a process limitation, not considered patentable during the prosecution of product claims before the USPTO. As to the claimed release rates and profiles, they are met by the nature of the wall and laminae as described above. As to the claimed location of the second and third drug on the bottom and top side of the tablet respectively, the wall and laminae of Guittard et al surround the core (see Figure 2), therefore including the top and bottom sides of the disclosed tablet.

Claims 1-42, 57-82, 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Guittard et al (US 4,576,604) in view of Theeuwes et al (US 4,576,604) and Johnson et al (US 6,171,618).

Guittard et al is described above. Cellulose acylates are specified as semi-permeable materials (column 8 lines 10-12). The reference does not teach the claimed ratios of layers, the claimed pseudoephedrine and cetirizine, the claimed polyvinyl

acetate, the claimed same release profiles, nor the claimed loci of the active agents in the device.

Johnson et al teach a dosage form combining controlled release of pseudoephedrine from the core of a dosage form and immediate release of cetirizine to ensure patient compliance. (column 1 lines 42-64).

It would have been obvious to one of ordinary skill to deliver pseudoephedrine from the core and cetirizine from the immediate release lamina of the Guittard et al device to achieve the beneficial effect of ensuring patient compliance in view of Johnson et al. As to the claimed ratios of layers, the examples in Guittard et al demonstrate suitable amounts; optimal ratios may be achieved by routine experimentation absent a showing of criticality. As to the claimed same release profiles, one of ordinary skill would adjust the release rates to achieve optimum release by routine experimentation, absent a showing of criticality. As to the claimed polyvinyl acetate, Theeuwes et al teach the equivalence of acylated polysaccharides to the claimed polyvinyl acetate as a semi-permeable material (column 10 lines 19-32). A suitable range of polysaccharide size is disclosed (column 8 line 53-column 9 line 9). Thus, absent a showing of criticality, the substitution of polyvinyl acetate for cellulose acetates is a mere design choice. As to the claimed molecular weight range, an optimum such range can be determined by routine experimentation, absent a showing of criticality, given the disclosed polysaccharide chain length.

No claims allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Edward J. Webman whose telephone number is 571-272-0633. The examiner can normally be reached on M-F from 8 AM to 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, G. Kunz, can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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PRIMARY EXAMINER
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